



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 15 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Nicholas C. Caro, M.D.
4145 W. Peterson, Suite 200
Chicago, Illinois 60640

Dear Dr. Caro,

The Food and Drug Administration (FDA) inspected your medical practice located at the above address on April 23, 1997, and determined that you have an unapproved excimer laser system, which was manufactured by Photon Data, Inc., Winter Park, Florida and assembled by [REDACTED]. Excimer laser systems are considered to be devices within the meaning of section 201(h) of the Food, Drug and Cosmetic Act (the Act). Excimer laser systems are Class III devices which are required to have in effect an approved application for premarket approval (PMA) or an approved Investigational Device Exemption (IDE).

On January 24, 1997, you submitted an application for an IDE for your excimer laser system for use in refractive eye surgery. On February 14, 1997, the Office of Device Evaluation (ODE) at FDA's Center for Devices and Radiological Health (CDRH) sent you a letter disapproving your IDE application. You may not use your excimer laser system to treat human subjects until you have received either an approved PMA under section 515(a) of the Act, or an approved IDE under section 520(g).

Your excimer laser system is adulterated under section 501(f)(1)(B) of the Act because it is a Class III device under section 513(f), which is required to have in effect an approved PMA or an approved IDE, and no such PMA or IDE is in effect for it. Medical devices used by physicians in the course of their practice to treat patients are "marketed" and "held for sale" within the meaning of the Act. Further, your continued use of this device to treat patients is also a violation of the Act.

In addition, your excimer laser system must comply with the requirements of Federal Performance Standards for lasers which are found in 21 CFR Title 21 of the Code of Federal Regulations, Part 1040. We acknowledge receipt of a Laser Product Report from you for this excimer laser system. However, FDA found this Report to be deficient. Therefore, your excimer laser system is in violation of the Federal Performance Standards for lasers.

Please note that FDA does not consider your excimer laser to be a custom device. Section 520(b) of the Act establishes five conditions, each of which must be met by a device to be a custom device. The Act's custom device definition requires that the device be made to meet either the specific anatomical requirements of an individual patient or the special needs of an individual practitioner; a practitioner's special needs may be either an individual anatomical need or a special practice need that is not shared by other physicians.

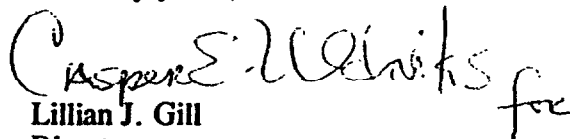
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We do not believe the requirements of your medical practice are unique because they are shared by numerous other health professionals. In addition, we do not believe your device is designed to meet any special anatomical needs that you or an individual patient of yours may have. Accordingly, your laser is not a custom device and is not exempt from the requirement under the Act that this device must have an approved PMA or IDE in effect.

Please notify this office within 15 working days of your receipt of this letter as to what, if any, actions you are taking or plan to take to bring your device into compliance with the Act. Your response should also clearly state whether or not you have ceased using the device to treat patients. Failure to immediately and completely cease clinical use of the device upon receipt of this letter, and failure to bring your device into compliance with the Act, may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Please note that no extensions of the 15 day response period will be given.

Your response should be sent to the attention of Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch (HFZ-331) at the letterhead address. In addition, please send a copy of your response to Mr. Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 S. Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606. If you have further questions, please contact Mary-Lou Davis at (301) 594-4613 extension 127 or FAX: (301) 594-4638.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Lillian J. Gill", with a stylized flourish at the end.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health